REMARKS

By this amendment, the specification is amended to correct the language of the priority claim in the first sentence following the title of the instant application. The priority claim was previously entered as an amendment in the transmittal papers filed with the application on December 28, 2000, and is thus timely filed under 37 C.F.R. § 1.78. As such, no new matter has been added by this amendment.

Claims 75, 97, 99-101, 111, 112, 122, 129, 132, and 133-147 were pending in the instant application. By this amendment, claim 75 has been amended and claims 133-147 have been canceled, without prejudice to applicants' right to pursue the canceled claims in other applications. Claim 75 has been amended to indicate that the mammal being treated has an autoimmune disorder. Support for the amendment to claim 75 is found at page 9, lines 33 and 36.

Thus, claims 75, 97, 99-101, 111, 112, 122, 129, and 132 are pending in the instant application. Applicants respectfully request that the amendments and remarks made herein be entered into the record of the instant application.

THE REJECTION UNDER 35 U.S.C. § 102(e), FOR ANTICIPATION, SHOULD BE WITHDRAWN

The Examiner has rejected Claims 75, 97, 99-101, 111, 112, 122, 129, and 132 under 35 U.S.C. §102(e) as allegedly being anticipated by Strickland *et al.* (U.S. Patent No. 6,156,311). Strickland describes the use of an anti-LRP (*i.e.*, an anti-CD91 antibody) for use in treating Alzheimer's disease, which the Examiner contends is a dense deposit disease. Applicants believe that the rejection is in error, for the reasons discussed below.

In order for a reference to anticipate a claim, each and every element of the claim must be disclosed in that one reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1985). "Anticipation under Section 102 can be found only if a reference shows exactly what is claimed . . ." *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707 (Fed. Cir. 1984).

Applicants assert that the claims are not anticipated by Strickland because

Strickland does not disclose methods for use in treating an autoimmune disorder, as the Examiner contends. The Examiner's position is based on the faulty characterization of Alzheimer's disease as dense deposit disease, leading to the erroneous conclusion that because Strickland teaches the use of anti-LRP (*i.e.*, anti-CD91) antibodies to treat Alzheimer's disease, it therefore teaches use of anti-LRP (*i.e.*, anti-CD91) antibodies to treat dense deposit disease, an autoimmune disorder. As discussed in further detail below, Alzheimer's disease is not dense deposit disease, a renal condition and an autoimmune disorder characterized by immune complex deposits in the kidney, but rather a neurological disorder of the central nervous system that is not classified as an autoimmune disorder.

The Examiner contends that, because Alzheimer's disease involves deposits of extracellular plaques, and because the specification has not defined "dense deposit disease," the claims read on the treatment of Alzheimer's disease and thus are anticipated by Strickland. Applicants respectfully disagree. The skilled artisan would clearly understand dense deposit disease to mean a kidney disease caused by deposits in the basement membranes of the kidneys and not Alzheimer's disease. According to the art-recognized reference, The Merck Manual of Diagnosis and Therapy, dense deposit disease is type II membranoproliferative glomerulonephritis, an immune-mediated disorder characterized by chronic immune complex deposition in the glomeruli of the kidneys (see, The Merck Manual of Diagnosis and Therapy, 1999, Beers and Berkow eds., Merck Research Laboratories, Whitehouse Station N.J., pages 1871 and 1872; hereafter "The Merck Manual of Diagnosis and Therapy", submitted herewith as Exhibit A). As described therein, dense deposit disease is characterized by electron dense deposits in the kidney that partially replace lamina densa causing a thickening of the glomerular basement membrane, which are entirely different from the plaque deposits in the brain described by Strickland. Thus, Alzheimer's disease is not dense deposit disease and is not an autoimmune disorder, and does not fall within the scope of the claimed invention.

Moreover, the use of the terms "dense deposit disease" and "Alzheimer's disease" in the specification is entirely consistent with these well established art-recognized definitions. The specification clearly distinguishes between dense deposit disease and Alzheimer's disease. For example, dense deposit disease is characterized in the specification as an autoimmune disorder (see, *e.g.,* page 69, line 29 through page 70, line 1), whereas, in contrast, Alzheimer's disease is distinguished from, and mentioned in the alternative to, an

autoimmune disorder (see, *e.g.*, page 7, lines 33-37; and page 13, lines 12-16). The specification lists an array of diseases which fall within the category of autoimmune disorders, and Alzheimer's disease is not one of them (see, *e.g.*, page 69, line 29 through page 70, line 1). Thus, whereas dense deposit disease is clearly considered an autoimmune disorder both in the art and in the specification, Alzheimer's disease is not considered a dense deposit disease and is not considered an autoimmune disorder, neither in the art as a whole, nor as defined in the specification.

The skilled artisan would not view Strickland as teaching anything regarding autoimmune disease since, at the time of filing of the instant application, Alzheimer's disease was not considered an autoimmune disorder. The Examiner, however, cites Weiner *et al.* (Nature, 2002, 420: 879-884) for the proposition that Alzheimer's disease is now implicated as having "inflammatory and immune components amenable to treatment by anti-inflammatories and immunotherapeutic approaches," presumably implying that Alzheimer's disease is an autoimmune disorder and therefore would fall within the scope of the claimed invention. However, this post-filing date reference does not alter what the skilled artisan would understand reading Strickland at the relevant time, *i.e.*, the filing date of the instant application.

Moreover, Weiner does not disclose or even suggest that Alzheimer's disease is considered an autoimmune disorder. Autoimmune disorders are defined by The Merck Manual of Diagnosis and Therapy as, "[D]isorders in which the immune system produces autoantibodies to an endogeneous antigen, with consequent injury to tissues" (see p. 1061-1064). Clearly, the disclosure that a disease has inflammatory and immune components amenable to treatment by anti-inflammatories and immunotherapeutic approaches does not mean that the disease is an autoimmune disorder. In fact, Weiner specifically distinguishes Alzheimer's disease ("AD") from a true autoimmune disorder, muscular sclerosis ("MS") in the following passage:

> "[A]lthough it has become increasingly recognized that inflammation may be important in the neuropathological damage that occurs in AD, unlike MS the inflammation in AD seems to arise from inside the CNS with little or no involvement of lymphocytes or monocytes beyond their normal surveillance of the brain. The inflammatory cytopathology...is thought to represent a *secondary response* to the early accumulation of Aβ in the brain." (Emphasis added)

Weiner et al. page 882, ¶ abridging first and second columns). Thus, even in view of the disclosure of Weiner, Alzheimer's disease would not be considered an autoimmune disorder. As such, the claimed invention does not encompass Alzheimer's disease.

In summary, Strickland does not disclose all of the elements of the claimed methods for treating an autoimmune disorder. In particular, Strickland does not disclose administering an antibody to a mammal having an autoimmune disorder for treatment of the autoimmune disorder, because Alzheimer's disease is not an autoimmune disorder. Thus, Strickland does not anticipate the claimed methods for treating an autoimmune disorder.

In view of the remarks above, Strickland does not disclose or suggest the claims of the instant invention. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C.§ 102(b) should be withdrawn.

CONCLUSION

An allowance of the application is earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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